UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,315	04/08/2008	Lawrence Solomon	1322-035	2612

47888 7590 09/30/2010

HEDMAN & COSTIGAN, P.C.
1230 AVENUE OF THE AMERICAS
7th floor
NEW YORK, NY 10020

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
09/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,315	SOLOMON ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7-12 and 15-33* is/are pending in the application.

4a) Of the above claim(s) *27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 7-12, 15-26 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 09/07/10 are acknowledged.

2. Claims 27-32 were withdrawn. Claims 2, 4-6, and 13-14 were cancelled.

3. Claims 1, 3, 7-12, 15-26 and 33 are included in the prosecution.

Response to Arguments

Rejection of claims under 35 USC § 103(a)

4. Applicant's arguments, see Page 7, filed 09/07/10, with respect to the following rejections have been fully considered and are persuasive.

- Rejection of claims 1, 3, 7-12, 15-17, 21-26, and 33 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Conte et al. (US 6,183,778 B1)
- Rejection of claims 17-18 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Conte et al. (US 6,183,778 B1) and further in view of Addicks et al. (US 5,041,430)
- Rejection of claims 17 and 19 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Conte et al. (US 6,183,778 B1) and further in view of Eberlin et al. (US 3,696,091)
- Rejection of claims 17 and 20 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Conte et al. (US 6,183,778 B1) and further in view of Franz et al. (US 6,555,581 B1)

Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447.

Due to the new ground(s) of rejection this action is made Non-Final.

Claim Rejections - 35 USC § 103

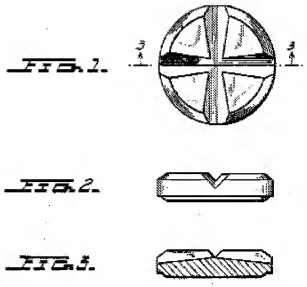
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 3, 7-12, 15-17, 21-26 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447).

The claimed invention is a pharmaceutical tablet comprising a first segment one face of which is contiguous with and substantially identical to first and second unitary segments that contain a drug or drugs, where the first segment contains either an undetectable amount of a drug or a pharmacologically ineffective amount of drug. The first segment has a score on its surface positioned between the first and the second unitary segments.

Langauer teaches a tablet having a breaker score assuring accurate and easy breakage into predetermined portions (Abstract). Fig. 1 is a top view of the tablet, Fig. 2 is a right side view and Fig. 3 is a cross-sectional view taken on line 3-3 of Fig. 1.



Langauer teaches a tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface (Col. 4, claim 1, lines 6-23). Langauer also teaches that "the sectioning of scored tablets is designed so that the active substance contained in each tablet (medicaments, active pharmacological agents) can be administered fully or to the extent of half or a quarter, depending on prescription or requirement" (Col. 1, lines 26-30). Langauer teaches variations in weight and in content of the active substances in the separated portions of scored tablets (Col. 1, lines 38-51).

Langauer does not expressly teach a first segment that contains either an undetectable amount of a drug or a pharmacologically ineffective amount of drug.

Ting teaches a multiplex drug delivery system suitable for oral administration containing at least two distinct drug dosage packages and substantially enveloped by a scored film coating that allows the separation of the multiplex drug delivery system into individual drug dosage packages (Abstract, Page 2, lines 18-34, Page 3, line 17 to Page

4, line 12, Page 6, lines 5-14, claims 1-37). Fig. 1 shows an oblong tablet scored in the middle to allow for easy breaking of the tablet (Page 6, lines 13-14).

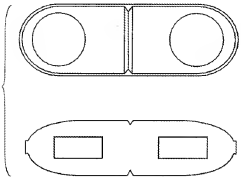


FIG. 1

The extended release compartment can comprise a combination of a hydrophilic and a hydrophobic material (Page 2, lines 18-34) and is scored (Page 6, lines 5-12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface, as taught by Langauer, combine it with the tablet that contains two immediate release compartments substantially enveloped by a scored extended release compartment, as taught by Ting, and produce the instant invention.

One of ordinary skill in the art would combine the tablets of Langauer and Ting because it is obvious to use a known technique (scoring tablets in order to assure accurate and easy breakage into predetermined portions – as taught by Langauer) to improve similar products (such as the tablets with a scored extended release compartment – as taught by Ting). Please see MPEP 2141.

Applicant has not established that the art does not have an ineffective or an undetectable amount of drug. Applicant has not identified any ranges/amounts deemed to be ineffective or undetectable.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 1, 3, and 7-9, the pharmaceutical tablet comprising a first segment one face of which is contiguous with substantially identical first and second unitary segments that contain a drug or drugs would have been obvious over the tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface, as taught by Langauer (Col. 4, claim 1, lines 6-23) in view of the tablet containing a scored extended release compartment that envelopes the immediate release compartments (Abstract, Page 2, lines 18-34, Page 6, lines 5-14, claims 1-37, Fig. 1). Regarding the limitation of a first segment that contains either an undetectable amount of a drug or a pharmacologically ineffective amount of drug and the limitations of claims 7-9 would have been obvious over the scored extended release compartment that envelopes the immediate release compartments, as taught by Ting (Abstract, Page 2, lines 18-34, Page 6, lines 5-14, claims 1-37, Fig. 1). Since Ting teaches that the extended release compartment can comprise a combination of a hydrophilic and a hydrophobic material and does not require the inclusion of a drug in

an embodiment of the extended release compartment, this reference renders obvious the limitation of a segment containing either an undetectable amount of a drug or a pharmacologically ineffective amount of drug (Page 2, lines 18-32).

Regarding instant claim 3, the one or more additional unitary segments in addition to the first and second unitary segments that are optionally present and are derived from the same layer or layers as said first unitary segment would have been obvious over the two or more discrete segments of the divisible tablet, as taught by Langauer (Fig. 2) in view of the multiplex drug delivery system containing at least two distinct drug dosage packages taught by Ting (Fig. 1).

Regarding instant claim 10, the limitation of the first segment that is derived from a granulation that does not contain a drug would have been obvious over the granulation (Page 5, lines 27-30) in view of the extended release compartment that may not contain a drug (Page 2, lines 18-32) as taught by Ting.

Regarding instant claim 11, the limitation of additional unitary segments that are contained in the tablet which are compositionally different from the composition of said first unitary segment and said second unitary segment and are derived from a granulation containing a drug would have been obvious over the variations in content of the active substance as taught by Langauer (Col. 1, lines 38-42).

Regarding instant claim 12, the limitation of the first unitary and the second unitary segments that are outer segments would have been obvious over the divisible tablets illustrated by Figures 1-3 by Langauer.

Regarding instant claim 15, the limitation of a substantially vertical score in said first segment, said score being vertically aligned with the center of the space between said first unitary segment and said second unitary segment would have been obvious over the divisible tablet taught by Langauer (Figures 1-3).

Regarding instant claim 16, the limitation of two additional unitary segments which are compositionally identical would have been obvious over the two or more discrete segments of the divisible tablet taught by Langauer (Figure 1). One of ordinary skill in the art would find it obvious to include additional segments based on the desired fractions or doses of the whole tablet.

Regarding instant claims 17 and 33, the limitation of the drugs would have been obvious over the drugs including non-steroid anti-inflammatory drugs (used for the treatment of pain) taught by Ting (Page 3, line 17 to Page 4, line 12).

Regarding instant claims 21-22, the limitation of the first segment adjoining a plurality of unitary segments on the side of said first segment that is opposite the surface adjoining said first and second unitary segments would have been obvious over the divisible tablet, as illustrated in Figure 1 by Langauer.

Regarding instant claims 23-26, the methods of breaking a pharmaceutical tablet would have been obvious over the tablet that may be divided into discrete segments and administered, as taught by Langauer (Abstract and Figures 1-3).

7. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Addicks et al. (US 5,041,430).

The Langauer and Ting references are discussed above and that discussion is hereby incorporated by reference.

Langauer and Ting do not expressly teach warfarin as the drug in the tablet.

Addicks teaches a multilayer tablet that comprises warfarin (Col. 7, line 46 to Col. 8, line 9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface, as taught by Langauer, combine it with the tablet that contains two immediate release compartments substantially enveloped by a scored extended release compartment, as taught by Ting, further combine it with the tablet that comprises warfarin, as taught by Addicks, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the breakable tablet assuring accurate and easy breakage into predetermined portions, as taught by Langauer (Abstract) and Ting (Abstract).

Regarding instant claims 17-18, the limitation of warfarin would have been obvious over the warfarin in the multilayer tablet taught by Addicks (Col. 7, line 46 to Col. 8, line 9).

8. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Eberlin et al. (US 3,696,091).

The Langauer and Ting references are discussed above and that discussion is hereby incorporated by reference.

Langauer and Ting do not expressly teach digoxin as the drug in the tablet.

Eberlin teaches a tablet that comprises digoxin (Col. 12, lines 20-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface, as taught by Langauer, combine it with the tablet that contains two immediate release compartments substantially enveloped by a scored extended release compartment, as taught by Ting, further combine it with the tablet that comprises digoxin, as taught by Eberlin, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the breakable tablet assuring accurate and easy breakage into predetermined portions, as taught by Langauer (Abstract) and Ting (Abstract).

Regarding instant claims 17 and 19, the limitation of digoxin would have been obvious over the digoxin in the tablet taught by Eberlin (Col. 12, lines 20-45).

9. Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Franz et al. (US 6,555,581 B1).

The Langauer and Ting references are discussed above and that discussion is hereby incorporated by reference.

Langauer and Ting do not expressly teach levothroxine as the drug in the tablet.

Franz teaches a tablet that comprises levothyroxine sodium (Col. 17, Table 1, lines 10-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tablet having opposite generally plane surfaces, where one of the plane surfaces has a score on the surface, as taught by Langauer, , combine it with the tablet that contains two immediate release compartments substantially enveloped by a scored extended release compartment, as taught by Ting, further combine it with the tablet that comprises levothyroxine, as taught by Franz, and produce the instant invention.

One of ordinary skill in the art would be motivated to do this because of the advantage of the breakable tablet assuring accurate and easy breakage into predetermined portions, as taught by Langauer (Abstract) and Ting (Abstract).

Regarding instant claims 17 and 20, the limitation of levothroxine would have been obvious over the levothyroxine in the tablet taught by Franz (Col. 17, Table 1, lines 10-22).

MAINTAINED REJECTIONS

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 3, 7-12, 15-26 and 33 **remain** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 14 and 17 of copending Application No. 11/441,455 (the '455 Application).

Although the conflicting claims are not identical, they are not patentably distinct from each other. The difference between instant claims and those of the '455 Application is that instant claims require unitary segments. However, one of ordinary skill in the art would find it obvious to design the tablet with unitary segments in order to accomplish partial dosing of the active.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1, 3, 7-12, 15-26 and 33 **remain** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-15 and 20 of U.S. Patent No. 7,329,418 (the '418 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference of immediate release as required by the claims of the '418 patent would have been an obvious variation to one of ordinary skill in the art.

13. Claims 1, 3, 7-12, 15-26 and 33 **remain** rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 6-11 of U.S. Patent No. 7,318,935 (the '935 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference of tablet height greater than tablet width as required by the claims of the '935 patent would have been an obvious variation to one of ordinary skill in the art.

Response to Arguments

14. The terminal disclaimers filed over copending Application No. 11/441,455, U. S. Patent No. 7,329,418, and U.S. Patent No. 7,318,935 on 09/07/10 are acknowledged. Until such time that the terminal disclaimers are approved the rejections under obviousness type double patenting will be maintained.

Conclusion

15. Due to the new grounds of rejection, this action is made non-final.

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615